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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/602,839	06/23/2000	Markus Pompejus	BGI-127CP	9461
959	7590	12/19/2003	EXAMINER	
LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109			LU, FRANK WEI MIN	
			ART UNIT	PAPER NUMBER
			1634	
DATE MAILED: 12/19/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/602,839

Applicant(s)

POMPEJUS ET AL.

Examiner

Frank W Lu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-7,10-16,36-38 and 40-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-7,10-16,36-38 and 41-43 is/are rejected.
- 7) ☒ Claim(s) 40 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Response to Amendment

1. Applicant's response to the office action filed August 13, 2003 has been entered. The claims pending in this application are claims 1, 4-7, 10-16, 36-38, and 40-43. Rejection and/ or objection not reiterated from the previous office action are hereby withdrawn in view of the amendment filed on August 13, 2003. The following rejections are based on new added claims filed on August 13, 2003.

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered. Although applicant indicates that "[A]pplicants respectively submit that they intend to file an Information Disclosure statement for the instant application in due course" (see applicant's remarks, page 7, fifth paragraph), the listing of references in the specification will not be considered if these references are not listed as IDS.

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Claim Objections

3. Claims 1, 5-7, and 40 are objected to because of the following informality: “a full complement therefore” should be “the full complement thereof”.
4. Claims 36 and 37 are objected to because of the following informality: “derived from” should be “derived from SEQ ID NO:1”.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 4-7, 10-16, 36-38, and 41-43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is referred to the interim guidelines on written description published on December 21, 1999 in the Federal Register at Volume 64, Number 244, pp.71427-71440.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111 (Fed. Cir. 1991), clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed.” *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1117.

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The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1116.

In this instant case, since, from the specification, it is unclear that SEQ ID NO: 1 is a partial or complete cDNA or genomic sequence, an isolated nucleic acid molecule recited in claims 1 and 9-16, is read as any kind of isolated nucleic acid molecule having SEQ ID NO: 1 and can be read as a chromosome having SEQ ID NO: 1. Since SEQ ID NO: 2 does not start with Met, SEQ ID NO: 2 is a partial protein sequence.. An isolated nucleic acid molecule recited in claims 4 and 41 is read as any kind of isolated nucleic acid molecule that can encode a polypeptide comprising or consisting of an amino acid sequence of SEQ ID NO: 2. Since, from the specification, it is unclear that SEQ ID NO: 1 is a partial or complete cDNA or genomic sequence and SEQ ID NO: 2 is a partial protein sequence, an isolated nucleic acid molecule recited in claim 5 is read as any kind of nucleic acid molecule which encodes a naturally occurring allelic variant of a *Corynebacterium glutamicum* polypeptide comprising the amino acid sequence of SEQ ID NO: 2 wherein the isolated nucleic acid molecule can hybridize to the full complement of a nucleic acid molecule consisting of SEQ ID NO: 1 in 6X SSC at 45 °C. Although the Table 1 in the specification shows that SEQ ID NO: 2 is a protein translation elongation factor G, since SEQ ID NO: 2 is a partial protein sequence, it is unclear whether SEQ ID NO: 2 can function as a protein translation elongation factor G or not. Furthermore, the specification does not provide any evidence that SEQ ID NO: 2 can function a protein translation elongation factor G. Therefore, the limitation “wherein said nucleic acid molecule encodes a polypeptide which is capable of functioning as a protein translation elongation factor G” recited in claims 5, 6, and 36-38 will not

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be considered in the rejection. Since, from the specification, it is unclear that SEQ ID NO: 1 is a partial or complete cDNA or genomic sequence, an isolated nucleic acid molecule recited in claims 6 and 42 is read as any kind of nucleic acid which has at least 90% identity with the nucleotide sequence having SEQ ID No: 1. An isolated nucleic acid molecule recited in claim 7 is read as any kind of isolated nucleic acid comprising a fragment of at least 15 nucleotides of the nucleotide sequence of SEQ ID NO: 1 and can be read as a chromosome having at least 15 nucleotides of SEQ ID NO: 1. A host cell recited in claim 36 is read as a host cell comprising any kind of nucleic acid molecule because claim 36 does not limit the extent, percentage, and location of the disruption and the nucleic acid molecule with the disruption is not considered as the same nucleic acid molecule having SEQ ID NO: 1. A host cell recited in claim 37 is read as a host cell comprising any kind of nucleic acid molecule because claim 37 does not limit the extent, percentage, and location of the modification and the nucleic acid molecule comprising more nucleic acid modifications as recited in claim 37 is not considered to be the same nucleic acid molecule as the nucleic acid having SEQ ID NO: 1. A host cell recited in claim 38 is read as a host cell comprising any kind of nucleic acid molecule because claim 38 does not limit the extent, percentage and location of the modification and the nucleic acid molecule comprising the modifications on the regulatory region as recited in claim 38 is not considered to be the same nucleic acid molecule as the nucleic acid having SEQ ID NO: 1. Although the specification adequately describes an isolated nucleic acid consisting of the nucleotide sequence of SEQ ID No: 1 and its corresponding protein sequence (SEQ ID NO: 2), claims 1, 4-7, 9-16, 36-38, and 41-43 encompass numerous unknown and unidentified nucleic acids that have polynucleotide

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sequence adding to 5', 3' and/or within the nucleotide sequence of SEQ ID No. 1 or nucleic acids encoding various variants of SEQ ID No. 1 that miss from the disclosure. It is unclear whether these variants of SEQ ID No: 1 can have the same functions as SEQ ID NO: 1 does. Therefore, the general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed.

With limited disclosure provided by the specification, the skilled artisan cannot envision all the possible variant nucleic acid sequences which would be homologous or hybridize but do not correspond to nucleotide sequence consisting of SEQ ID No: 1, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method used. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of identifying it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991).

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. Therefore, only an isolated nucleic acid molecule consisting of SEQ ID No: 1 and its corresponding protein sequence consisting of SEQ ID NO: 2 meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

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Response to Arguments

In page 10, last paragraph bridging to page 13, last paragraph of applicant's remarks, applicant argues that: (1) based on the definition of isolated nucleic acid molecule (see the specification, page 28, lines 7-11), "the claimed isolated nucleic acid molecules of claim 1, which comprise SEQ ID NO:1 do not contain surrounding chromosomal DNA."; (2) claims 4-6, 10-16, 36-38, and 40-42 are similar to Examples 14 and 15 shown in the PTO Revised Interim Written Description Guidelines Training Materials; and (3) "[A]pplicants' specification teaches how such polynucleotide fragments encoding polypeptides may be tested for activity (see, for example, page 40, lines 22-34 of the specification).".

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection. First, according to the definition, an isolated nucleic acid molecule is one which is separated from other nucleic acid molecules which are present in the natural source of the nucleic acid (see the specification, page 28, lines 7-11. Since the chromosome containing SEQ ID NO: 1 can be separated from other chromosomes, and it is known that different chromosomes contain different nucleotide sequences and claim 1 is a "comprising" claim, an isolated nucleic acid recited in claim 1 can be read as a chromosome having SEQ ID NO: 1. Second, relating to Example 14 in the PTO Revised Interim Written Description Guidelines Training Materials, applicant is comparing an apple with an orange since the claim in the Example 14 is directed to a protein and is not directed to an isolated nucleic acid, and a vector and host having the isolated nucleic acid as recited in claims 1, 4-7, 10-16, 36-38, and 41-43. Relating to Example 15 in the PTO Revised Interim Written Description Guidelines

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Training Materials, since SEQ ID NO: 1 in the Example 15 is the full-length complement (mRNA) of a full-length cDNA while it is unclear that SEQ ID NO: 1 in this instant application is a partial or complete cDNA or genomic sequence, the example 15 and claims 1, 4-7, 10-16, 36-38, and 41-43 is not comparable. Third, in page 40, lines 22-34 of the specification, the specification does not teaches "how such polynucleotide fragments encoding polypeptides may be tested for activity" as suggested by applicant.

7. Claims 15, 16, and 43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for modulating in production of certain kind of fine chemical using a nucleic acid molecule consisting of SEQ ID NO: 1, does not reasonably provide enablement for modulating in production of any kind of fine chemical recited in claims 15, 16, and 43 in any kind of cell including bacteria using a nucleic acid molecule comprising SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claims 1 and 10-14 were not included in the rejection since these claims are directed to a nucleic acid molecule, a vector comprising the nucleic acid molecule, and a host cell comprising the nucleic acid molecule which are enabling in view of the specification.

In *In re Wands*, 858 F.2d 731,737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court considered the issue of enablement in molecular biology. The Court summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the

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presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims. The Court also stated that although the level of skill in molecular biology is high, results of experiments in molecular biology are unpredictable.

Claims 15 and 16 are drawn to a host cell having a nucleic acid comprising SEQ ID NO: 1 wherein a nucleic acid comprising SEQ ID NO: 1 is capable of modulating in production of any kind of fine chemical recited in claims 15 and 16 in any kind of cell. It is possible that a nucleic acid consisting of SEQ ID NO: 1 can modulate in production of a fine chemical selected from claim 16 in *Corynebacterium glutamicum*. However, the specification does not provide any evidence to show that a nucleic acid comprising or consisting of SEQ ID NO: 1 (see the specification, Table 1) can modulate in production of any one of fine chemicals selected from claim 16 in any kind of cell including bacteria. The evidence from an art search appears against the claimed invention as recited in claims 15 and 16. First, since it was well known in the art that protein synthesis in eucaryotes (ie., animal cells) and procaryotes (i.e. bacteria cells) required different ribosome subunits (see Text book of Biochemistry with Clinical correlations, edited by Thomas Devlin, third edition, 1992, page 725-727, specifically see Table 17.1), it is unclear whether a nucleic acid comprising or consisting of SEQ ID NO: 1, a protein from *Corynebacterium glutamicum* (possible protein translation elongation factor G) (see the specification, Table 1), can interact with ribosome subunits from an eukaryote and modulate in production of any one of fine chemicals recited in claims 15 and 16 in an eukaryotic cell. Second, since conserved nucleotide sequences of the protein translation elongation factor G among

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bacteria were 41-85% (Caldon et al., Molecular microbiology, 41, 289-297, 2001, see Table 1), it is unclear whether a nucleic acid comprising or consisting of SEQ ID NO: 1 (possible protein translation elongation factor G from *Corynebacterium glutamicum*) can function in any kind of bacteria strain to modulate in production of any one of fine chemicals recited in claims 15, 16, and 43. Third, it is known that disruption of certain kind of protein translation elongation factor in certain kind of cell does not affect survival of the cell. For example, disruption of ELF1 (an elongation like factor) in *Candida albicans* produces a mixture of large, irregular cells and apparently normal cells wherein the disrupted strains grow more slowly than wild type (Sturtevant et al., Microbiology, 144, 2311-2321, see abstract) and disruption of GTPBP1 (elongation factor 1 a) in mice did not affect functions of antigen-present cells (Senju et al., Mol. Cell. Biol., 20, 6195-6200, 2000, see abstract). These evidence suggested that other protein translation elongation factor(s) can at least partially replace functions of the disrupted elongation factor and a protein translation elongation factor can not modulate in production of any kind of fine chemicals in a cell. Without an evidence in the specification, it is unclear whether a nucleic acid comprising SEQ ID NO: 1 (possible protein translation elongation factor G from *Corynebacterium glutamicum* (see Table 1) can modulate in production of any kind of fine chemicals recited in claims 15 and 16 in a cell. With these unpredictable factors, the skilled artisan will have no way to predict the experimental results.

Thus, in view of the lack of guidance, working examples, breadth of the claims, the level of skill in the art and state of the art at the time of the claimed invention was made, it would have required undue experimentation to make and/or use the invention as claimed. These

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undue experimentation at least includes to test whether a nucleic acid molecule comprising or consisting of SEQ ID NO: 1 can modulate in production of any kind of fine chemical recited in claims 15, 16, and 43 in any kind of cell including bacteria.

Response to Arguments

In page 15, third paragraph bridging to page 16, second paragraph of applicant's remarks, applicant argues that: (1) “[A]pplicants respectfully submit that any experimentation that may be required to select and/or make the claimed nucleic acid molecules, and subsequently practice methods of expressing and a polypeptide of the invention resulting in the production of a fine chemical constitutes routine, not undue, experimentation, and therefore the specification clearly enables the pending claims.” since “[A]pplicants specification clearly describes methods for transfecting various types of host cells including prokaryotic or eukaryotic cells, using various vectors (see, c.g., page 38, line 30 through page 45, line 36 of Applicants' specification).”; (2) “one of skill in the art would recognize that prokaryotic genes can function in eukaryotic cells as well as in prokaryotic cells other than the cell types to which the gene is endogenous. For example, as illustrated by the abstract attached hereto as Appendix A (Feher, et al. (1983) Nature 17-23; 302 (5905):266), bacterial genes are routinely expressed in yeast cells.”; and (3) “the Examiner references a Text book of Biochemistry with Clinical correlations, edited by Thomas Devlin, third edition, 1992, page 725-727. Applicants respectfully submit that this reference states that ‘ribosome architecture has been highly conserved in evolution,’ and that ‘similarities between ribosomes and subunits of different sources are more

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obvious than the differences.’ (see page 725). Accordingly, one would expect the translation elongation factor G of the instant invention to interact with various ribosomes.”.

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection. First, the examiner agrees with applicant that various vectors can be transformed or transfected into various prokaryotic or eukaryotic cells. Since the claims are not limited to express the nucleic acid recited in claim 1 in a prokaryotic or eukaryotic cell but requires a protein that expressed by the nucleic acid recited in claim 1 can function in various different prokaryotic or eukaryotic cells (ie., the modulation in production of a fine chemical from said cells), applicant is comparing an apple with an orange. Since the specification does not show that a protein encoded by SEQ ID NO: 1 can function in various different prokaryotic or eukaryotic cells, an undue experimentation at least including to test whether a nucleic acid molecule comprising or consisting of SEQ ID NO: 1 can modulate in production of any kind of fine chemical recited in claims 15, 16, and 43 in any kind of cell including bacteria is required. Second, although ribosome architecture has been conserved in evolution and similarities between ribosomes and subunits of different sources are more obvious than differences, this statement does not mean that a protein encoded by SEQ ID NO: 1 can function in various different prokaryotic or eukaryotic cells. Third, although *Bacillus sphaericus* R modification methylase can function in yeast cell (see Appendix A), it does not mean that protein translation elongation factor G from *Corynebacterium glutamicum* can function in any kind of cell. Furthermore, there is no evidence to show that a protein encoded by SEQ ID NO: 1 can function in various different prokaryotic or eukaryotic cells to modulate any kind of fine chemical recited in claim 16.

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8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 36 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 36 is rejected as vague and indefinite because it is unclear how a complete disrupted nucleic acid molecule can still function as a protein translation elongation factor since the claim does not limit the extent and percentage of the disruption. Please clarify.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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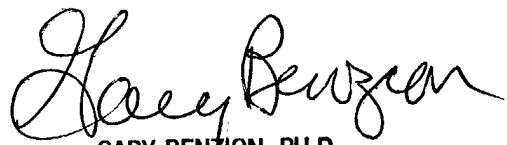
12. Claim 40 will be allowed if applicant can overcome above objection on claim 40.
13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270 (before January 13, 2004) or 571-272-0746 (after January 13, 2004). The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
PSA
December 11, 2003


GARY BENZION, PH.D
SUPERVISORY PATENT EXAMINER
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